EXHIBIT 13

Steward

Office of Corporate Compliance & Privacy

Compliance and Privacy Law Awareness

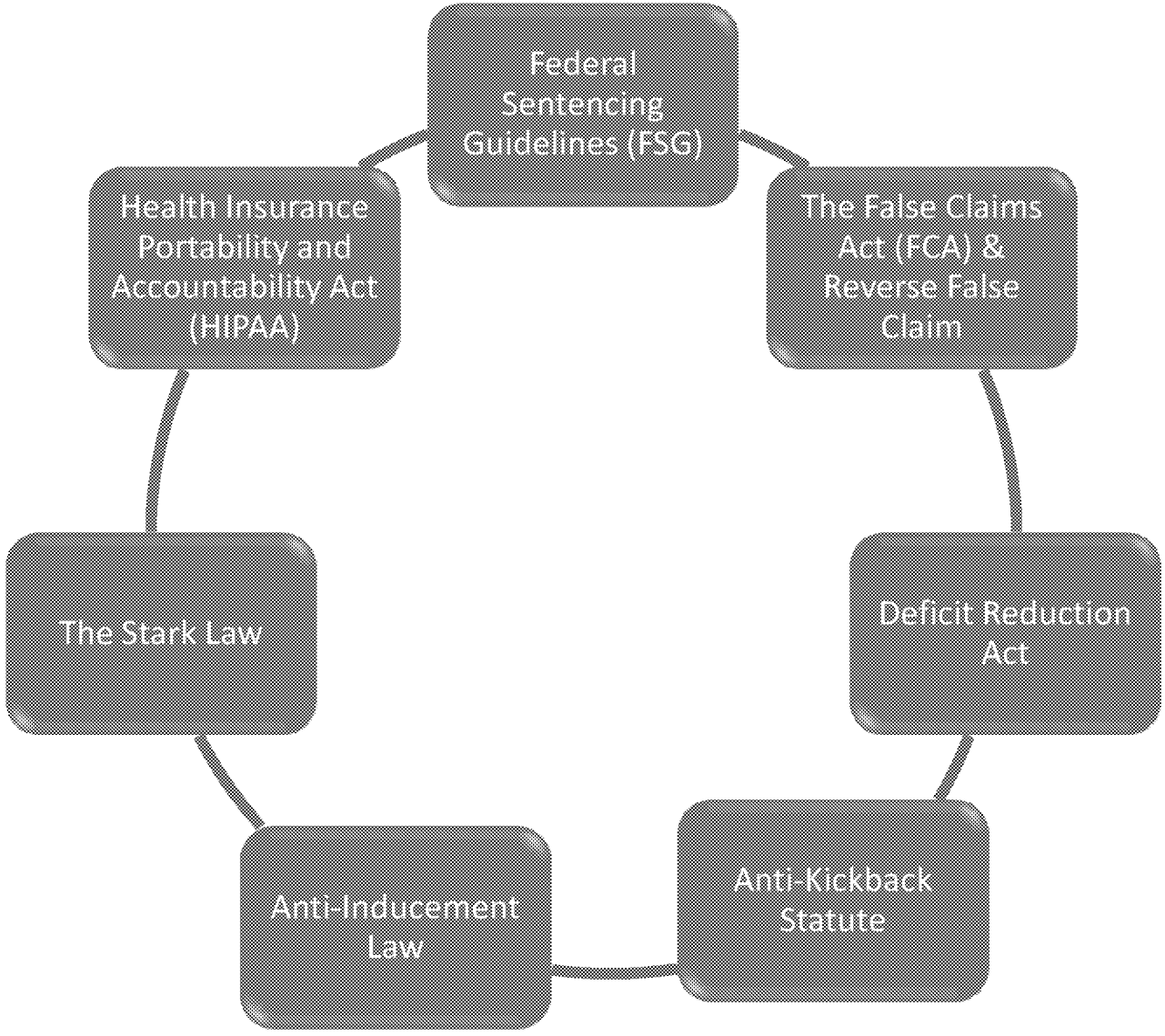
St. Elizabeth's Medical Center
November 2014

Objectives

✓Provide an overview to Board Members on key compliance and privacy laws

✓Discuss why these key laws are important for the role of a Board Member

Key Compliance and Privacy Laws



Federal Sentencing Guidelines (FSG)

What are the FSG and why are they importance?

- They are the basis for both having a compliance program and its specific structure (the 'seven elements')
  - OIG Voluntary Guidance build off of the seven elements
- They are used by courts to determine appropriate punishments for fraud and abuse violations (such as fines, debarment, probation etc.)
- They tie exposure to penalties to the effectiveness of the organization's compliance program.
  - Lighter sentences for corporations with "effective" compliance programs
  - Self-reporting, cooperation, or acceptance of responsibility
- They raise the significance of expectations for compliance programs

- They are used as the structure for developing Corporate Integrity Agreements when developing settlements for non-compliance.

- **The 2010 amendments to the federal sentencing guidelines require that a governing authority:**
  - **Is "knowledgeable" about the "content and operation" its compliance program**
  - **exercise reasonable over site over the implementation and effectiveness of the program**

The False Claims Act (FCA)

A federal law that makes it a civil and/or criminal offense to **knowingly** submit a false claim to the U.S Government for payment

"Knowingly":

- ✓Actual knowledge
- ✓Acted in deliberate ignorance or reckless disregard

FCA Requires:		
Claim information that is truthful and complete	Claims only for services that are medically necessary and performed by qualified personnel	Return of any identified government payments received in error

** Massachusetts also has a similar state FCA law**

FCA Examples…

Physician Supervision:

❖ *A company agreed to a $3.57 million settlement to resolve allegations that it violated the FCA by inappropriately billing for MRI scans using contrast without the appropriate direct supervision of a qualified physician. Regulations require that MRIs performed using a contrast agent be under direct supervision due to the risk of anaphylactic shock.*

Medically Unnecessary Services:

❖ *A hospital paid a $5.3 million dollar settlement to resolve allegations that it violated the FCA for billing Medicare and Medicaid programs for over-night hospital stays that were not medically necessary after patients received Gamma Knife Treatments.*

Overpayments:

❖ *An urgent care facility agreed to pay $10 million after it violated the FCA after they allegedly inflated billings (aka up coding) for urgent care services.*

Excluded Personnel:

❖ *A nursing facility agreed to pay a $28,542 settlement after they allegedly violated the FCA by improperly billing Medicare and Medicaid for services provided by an employee that was on the OIG list of excluded individuals.*

Reverse False Claim

Reverse False Claim Act: makes providers liable when overpayments are knowingly received and concealed to avoid refunding the government

Three Elements of a Reverse False Claim

Obligation: duty to repay an overpayment

Improper concealment or avoidance of a payment

Knowledge: Actual knowledge; acted in deliberate ignorance or reckless disregard

Providers are obligated to report and return 'identified' overpayments within 60 days.

Penalties for both FCA & Reverse FCA may range from $5,500 to $11,000 per false claim plus 3 times the amount of damages

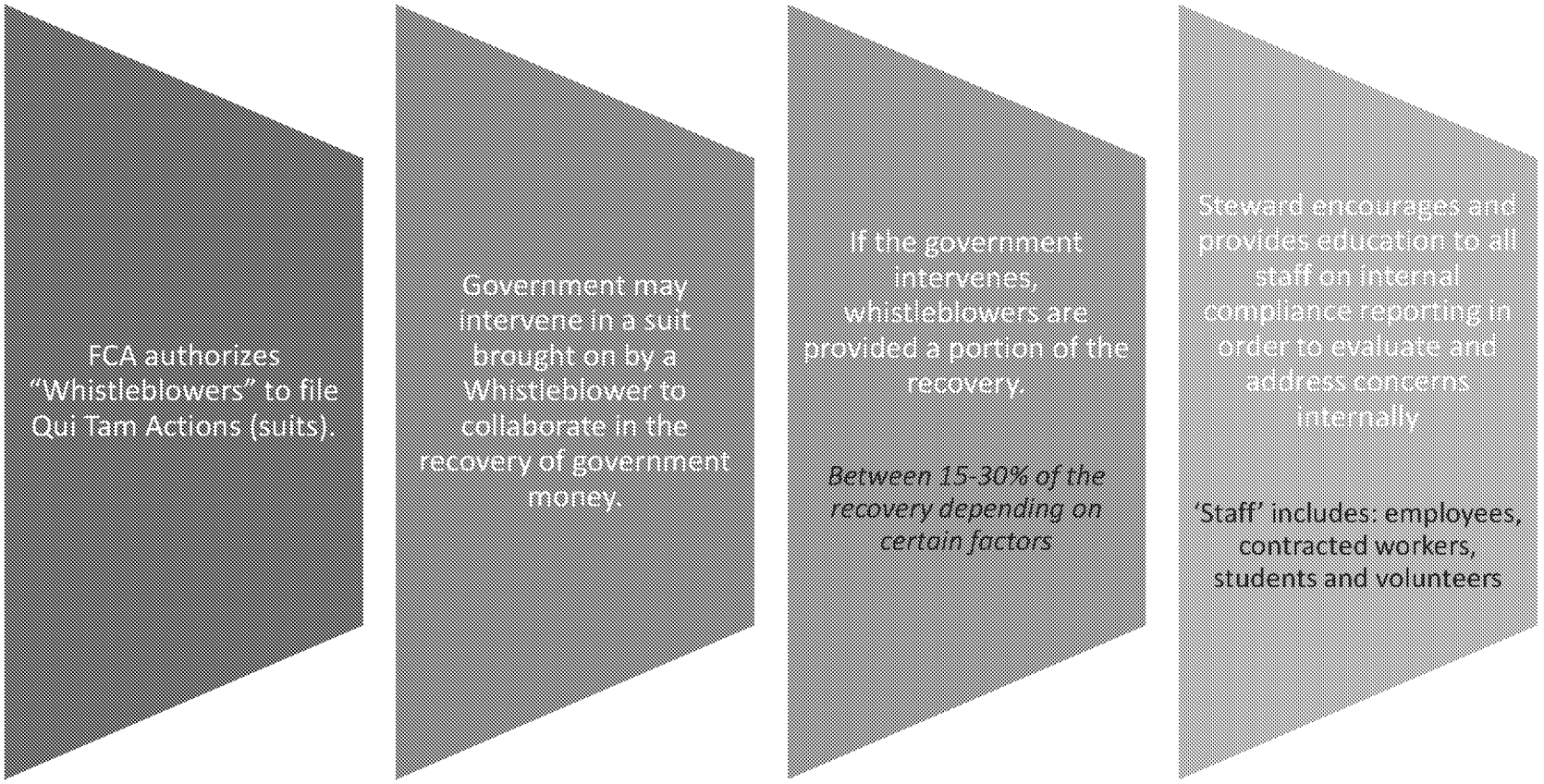
Reverse FCA Examples…

- *In 2012 a health plan agreed to pay $137.5 million to the federal government and nine states to resolve four lawsuits alleging FCA violations. The company allegedly inflated claims in order to avoid returning money to Medicaid as well as knowingly retained overpayments*

- *A hospital agreed to pay $750,000 to settle allegations that it violated the FCA after overbilling for cardiac testing and then failing to repay the overpayments after senior leadership learned of the error.*

- *A hospital agreed to pay $471,000 to settle false claims allegations after they knowingly failed to return overpayments. According to the settlement, the hospital regularly charged males for the drug Lupron at the higher reimbursed female dosage billing code. The hospital discovered the issue during an internal audit but failed to refund the overpayments to the government.*

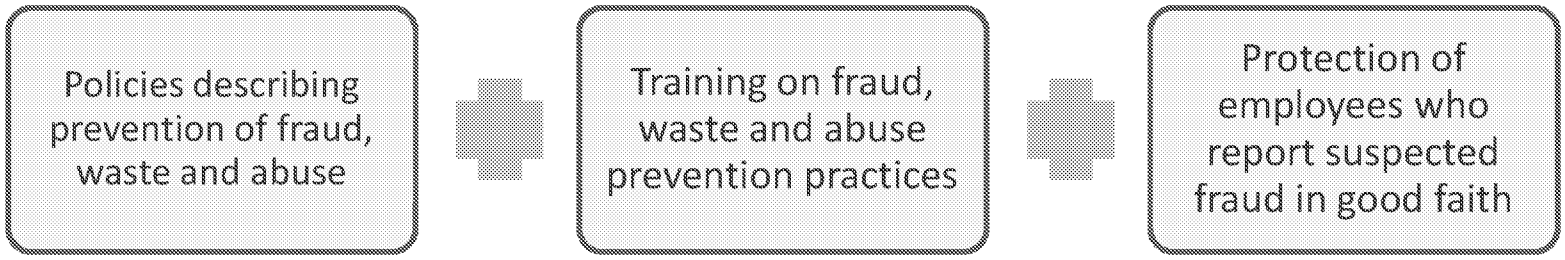
Whistleblowers and Qui Tam Actions



Steward Policies:
COM 4: Compliance Reporting
COM 13: Non-Retaliation

Deficit Reduction Act

Health care entities receiving $5 million+ in Medicaid payments during a year are required to establish written policies and procedures informing their employees about the False Claim Act and whistleblower protections.



For entities that received $5 million or more from Medicaid, annual attestations of compliance are signed by Steward entity senior leadership and submitted to the Massachusetts Department of Health and Human Services

Failure to comply with the DRA requirements may result in exclusion from the federal health program

Anti-Kickback Statute (AKS)

- The federal Anti-Kickback Statute ("Anti-Kickback Statute") is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business
- In some industries, you may reward others for referrals but in federal health care programs it is considered a crime.
- AKS is a statute designed to prevent improper services, such as over utilization, increased program costs, corruption of medical decision making.
- As such, AKS encompasses all payments to a referral source where one intent may be in exchange for patient services.
- AKS allows for certain exceptions. For example, payments to referral sources for space or equipment rental. In the context of exceptions, proper structuring of contracts is *critical* along with adherence to the *written* terms of the contract over time.

- Fines up to $50,000 for each improper act and damages up to 3 times the amount of remuneration
- Entity or individuals exclusion from the Medicare and other Federal health care programs
- Potential civil and criminal penalties

Anti-Kickback Examples

- *A medical supply company agreed to pay $1,140,260 for allegedly paying remuneration to customers that are members of its Medical Privileges Program in the form of points redeemable for products and services, which did not qualify as "discounts" or "rebates" under the anti-kickback statute.*

- *A medical device company agreed to pay $126,249.30 for allegedly violating the anti-kickback statute by providing customers (including physicians) an all-expense paid trip to the Masters Golf Tournament. The OIG concluded that the trips were intended to induce referrals.*

- *A medical center agreed to pay $10 million for allegedly paying patient "recruiters" to recruit homeless patients. The homeless patients were then provided medical treatments that were then billed to federal health programs, many of which were medically unnecessary.*

Anti-Inducement Law

A federal law that states that no one may give money, or anything else or value, to a patient to influence his or her choice of a provider for which services or items are paid for by a federal health care program.

What is an inducement?

- A provider routinely waives co pays for Medicare/Medicaid patients
- A provider offers $25 gift cards to patients who schedule an appointment in a new office building
- A clinic offers free blood pressure screenings and direct patients with high blood pressure to a hypertension program run by the provider.

What is not an inducement?

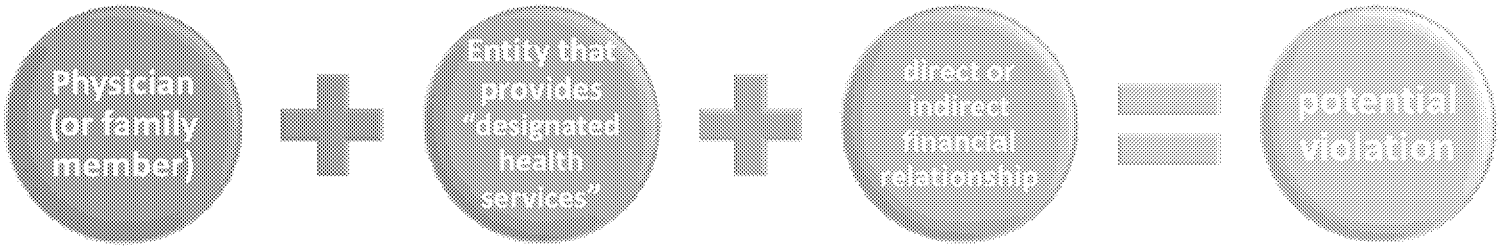
- Incentives to promote certain preventative care so long as they are not tied to the provision of other reimbursed Medicare or State health care services
- Inexpensive, non-cash items of nominal value *defined as under $10, not to exceed $50 annually*
- Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts
- Properly disclosed differentials in a health insurance plan's copayments or deductibles, such as lower payments for using preferred providers, mail order pharmacies, or generic drugs.

Additional exceptions are allowed for Accountable Care Organization activities.

The Stark Law

- A federal law that limits referrals where physicians have certain financial interests
- If a **physician** (or his or her immediate family member) has a **financial relationship** with an entity, the physician may not make **referrals** to that entity for **designated health services** for **Medicare** patients (unless an exception applies)
- If a prohibited referral is made, the entity may not bill Medicare for the service designated in the referral

Strict liability statute= proof of specific intent to violate the law is not required



unless the relationship meets an exception

Examples of Potential Stark Law Violations

- *A hospital provides administrative support services to a non-employed referring physician at no charge*
- *A physician refers Medicare or Medicaid patients to the physical therapy office in which he or she has financial interest*
- *A hospital has a contract with a medical group for a medical director and coverage service that expires in a week. To avoid disrupting the clinical services, the parties verbally agree on a new contract a hospital provides a physician with rental space for less than market value.*
- *A hospital compensates a physician group under contracts in excess of fair market value and took into account the volume of referrals from the physicians to the hospital in calculating compensation.*

Health Insurance Portability and Accountability Act (HIPAA)

Steward Entities must:

- ✓ Safeguard Protected Health Information (PHI)
- ✓ Provide patients with access to their PHI
- ✓ Tell patients how we will use their information
- ✓ Only use patient information as allowed by law

Examples of HIPAA Enforcement Activity

Not complying with HIPAA can result in significant penalties.

Office for Civil Rights (OCR) is responsible for enforcing the Privacy and Security Rules. There has been recent increased enforcement and scrutiny to ensure providers have implemented adequate safeguards to protect patient privacy.

- MGH paid $1M and implemented a corrective action plan including developing policies & procedures, training and semi-annual reporting to HHS after an employee left documents with sensitive information on the train. The records contained information about 192 infectious disease patients and were never recovered.

- Massachusetts Eye and Ear Infirmary paid $1.5M after the theft of an unencrypted personal laptop containing the e-PHI of patients and research subjects.

- A Concord, MA Dermatology practice paid $150,000 and implemented a corrective action plan after an unencrypted thumb drive containing the ePHI of approximately 2,200 individuals was stolen. The thumb drive was never recovered.

Corporate Integrity Agreements (CIA)

CIAs may be imposed by the OIG on health care providers in criminal and/or civil settlements under health care fraud statutes

The structure of CIAs is built from the 7 elements of an effective compliance program

Examples of recent CIAs

- A Texas hospital paid $1.4M and entered into a CIA to settle allegations that they submitted claims for rehab consultations that were never ordered. The CIA requires independent monitoring of the hospital's billing and clinical practices for five years.

- A Kentucky hospital paid $16.6M and entered into a CIA due to improper financial relationships with three doctors which allegedly led to unnecessary invasive cardiac procedures that were billed to Medicare and Medicaid. The CIA requires that the hospital reform their compliance program and commit to a third-party review of its claims to government payers for five years.

How Steward Works towards avoiding CIAs

- Implementation of an **effective** compliance program (" 7 elements")
- Policy Development and Review
- Annual and On-Going Education
- Annual Audit Work Plan
- Active Compliance Reporting Hot Line
- Investigation of all reported concerns
- Remediation Plans for identified risks

Senior leadership is engaged in Compliance and Privacy activities:

- ✓ Regular Compliance Committee meetings
- ✓ Quarterly Activity Reporting to Senior Leadership at this entity and to System Leaders

Board & Management Oversight Responsibilities